Request for Waivers of Informed Consent
(To be submitted with Application for IRB Review of Research)

Under special circumstances, investigators can request one of two kinds of waivers to obtaining written informed consent from research subjects. The first is a waiver of written documentation that informed consent was obtained. With this waiver, the investigator would be required to read or provide the informed consent form to a participant, but would not need to obtain the participant's signature on the consent form. Examples of when this waiver might be applicable would be some Internet or phone surveys or when signing the form might have some negative consequence for the subject. The second kind is waiver of informed consent. With this waiver, the investigator would not be required to give or to read an informed consent to a participant. This waiver may be approved by the IRB if the criteria below are met. It must be emphasized that these waivers will be given only when there are compelling reasons for doing so.

Please check whether you are requesting:

___Waiver of written documentation ___Waiver of informed consent

In order for your request to be considered, you must fully answer each of the following questions. Please provide supporting documentation where appropriate.

1. **Will the research in its entirety involve greater than "minimal risk" (Section 46.102(I))?** ***(Tab down)***

2. **Is it practical to conduct the research without the waiver/alteration?** ***(Tab down)***

3. **Will waiving/altering informed consent adversely affect subjects' rights and welfare?** ***(Tab down)***

4. **Will pertinent information be provided to subjects later, if appropriate?** ***(Tab down)***

5. **Can the research be practicably conducted without access to and use of the protected health information?** ***(Tab down)***

6. **Are the privacy risks to individuals whose protected health information is to be used or disclosed reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research?** ***(Tab down)***

7. **Is there an adequate plan to protect the identifiers from improper use and disclosure?** ***(Tab down)***

8. **Is there an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law?** ***(Tab down)***

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9. **Are there adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use of disclosure of protected health information would be permitted by this subpart?** ***(Tab down)***

_____	_____	_____
Principal Investigator's Signature	**Printed Name of P. I.**	**Date**

IRB Chair's Approval of Waiver of Consent: _____ **Date:** _____

IRB Chair's Nonapproval of Waiver of Consent: _____ **Date:** _____

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